

REMARKS

I. Status of the Claims

Claims 1-17 are pending in the application. Claim 11 is withdrawn pursuant to an election of species requirement, and thus claims 1-10 and 12-17 are under consideration and stand rejected under 35 U.S.C. §102(a) and §102(b). The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Rejections Under 35 U.S.C. §102

A. *Obremski et al.*

Claims 1-5, 7-10, 12 and 14-17 stand rejected as anticipated by Obremski *et al.* However, this reference teaches a detection method differing in its detection mechanism from that of the present invention. As such, the reference is not anticipatory.

Obremski teaches a binding assay comprising others the following features: (a) presence of an analyte in a sample to be detected; and (b) an array comprising a substrate and an analyte binding partner being specifically for said analyte to be detected. The subject of detection in Obremski is the analyte capture complex of (a) and (b). This is described in Obremski at, for example, page 9 in claim 1. Thus, the analyte to be detected is detected ***directly by means of the analyte capture complex.***

In contrast, the present invention discloses a different detection mechanism, namely, a competitive assay. This detection mechanism comprises, among others, the following three features: (a) an analyte in a sample to be detected (see e.g. specification as published, page 1, [0010]); (b) a complex consisting of a macromolecule to which at least two molecules identical to the analyte are coupled (see, e.g., specification as published, page 1-2, first sentence of

paragraph [0018]); and (c) a capture molecule coupled to a solid carrier, wherein the capture molecule is specific for the analyte, and thus also for the molecules identical to the analyte bound to the macromolecule (see, *e.g.*, specification as published, page 1, [0011]). Indeed, the subject of direct detection of the present invention is a complex of (b) and (c) (see, *e.g.*, specification as published, page 1, [0016]). However, this complex does not comprise the analyte of the sample as in Obremski.

This means that the analyte of the sample is not detected directly by a complex comprising said analyte. In fact, the analyte present in the sample is detected indirectly since the analytes compete for binding to the capture molecules with the molecules identical to the analytes, which are bound to the macromolecules. In other words, if none of the analytes to be detected are present in the sample, the molecules identical to the analytes bound to the macromolecules bind to the capture molecules, and the excitation of the macromolecule's fluorescence leads to a positive signal. In contrast, if the analyte is present in the sample, the molecules identical to the analytes bound to the macromolecules are prevented from binding to the capture molecules. An excitation of the macromolecule's fluorescence therefore fails to produce a positive signal (described in the specification as published, *e.g.*, on page 2 in paragraph [0011]).

Consequently, a significant difference between the present invention and the teaching of Obremski is the competitive detection mechanism of the present invention; thus, the subject-matter of the rejected claims is not anticipated. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. Shen *et al.*

Claims 1, 3, 5-7, 9, 10, 12-14, 16 and 17 stand rejected as anticipated by Shen *et al.* However, this reference teaches a detection method differing in its detection mechanism from that of the present invention. As such, the reference is not anticipatory.

Shen. teaches a similar method to that of Obremski, comprising the following features: (a) a target in a sample, which is to be detected; (b) a reporter ligand comprising an oligonucleotide identification tag and a portion being specifically for said target. The subject of detection in Shen *et al.* is the reporter ligand complex of (a) and (b). This is described in Shen *et al.*, *e.g.*, on page 2, paragraph [0011]. Thus, in Shen the target to be detected is detected directly by means of the reporter ligand complex.

As stated above, this is in contrast to the present invention, which discloses a different detection mechanism, namely, a competitive assay. Consequently, a significant difference between the present invention and the teaching of Shen is the competitive detection mechanism of the present invention; thus, the subject-matter of the rejected claims is not anticipated. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

III. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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